

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

1. Applicant

Quality Electrodynamics (QED)
700 Beta Drive, Suite 100
Mayfield Village, OH 44143
Phone (440) 484-2228

MAY - 1 2009

2. Contact

Christie Zydyk, MBA
VP & GM, Regulatory Affairs, Quality Assurance, & Corporate Communications

3. Date prepared:

April 8, 2009

4. Tradename

TxRx 1.5T CP Head Coil
TxRx 3T CP Head Coil

5. Common name

Coil, magnetic resonance, specialty

6. Classification

21 CFR 892.1000

7. Equivalent Device

MAGNETOM Symphony Head Coil and MAGNETOM Trio Head Coil manufactured by USA Instruments

8. Device Description

The 1.5T and 3T CP Head Coils are circularly polarized (CP) transmit and receive coils designed for magnetic resonance imaging of the head. The coils are designed for use with the Siemens MAGNETOM 1.5T Avanto/Espree and Siemens MAGNETOM 3T Trio a TIM/Verio systems respectively.

The coil elements are enclosed in a rigid plastic housing (polycarbonate) which is fire-rated and has impact and tensile strength (material data provided). The coils have a split-top mechanical design with a system cable on the posterior half of the coil. The inner cross section is shaped to fit the head anatomy. The coils include the following accessories: a mirror to reduce patient anxiety/claustrophobia and foam pads also to aid positioning and enhance patient comfort.

9. Intended Use

For use with a 1.5T Siemens Avanto/Espree or 3T Siemens Trio a TIM/Verio magnetic resonance scanner to produce diagnostic images of the head that can be interpreted by a trained physician.

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10. Comparison with Predicate Devices

510(k) #	Device	Manufacturer
K021262	MAGNETOM Symphony Head Coil	USA Instruments
K021330	MAGNETOM Trio Head Coil	USA Instruments

The 1.5T and 3T Siemens CP Head coils and predicate devices are designed for use in conjunction with magnetic resonance scanners to produce diagnostic images of the head that can be interpreted by a trained physician. The 1.5T and 3T Siemens CP Head Coils and the predicate devices have similar designs and are constructed of similar materials.

11. Conclusion

It is the opinion of Quality Electrodynamics that the 1.5T and 3T Siemens CP Head Coils are substantially equivalent to the above-listed legally marketed predicate devices. Use of the Quality Electrodynamics coils does not result in any new potential hazards



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY - 1 2009

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Quality ElectroDynamics
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K091114

Trade/Device Name: TxRx 1.5T and 3T CP Head Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: April 16, 2009
Received: April 17, 2009

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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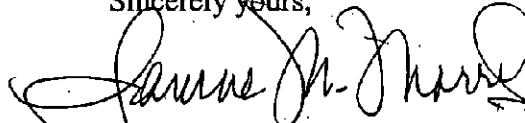
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091114

Device Name:

TxRx 1.5T CP Head Coil

TxRx 3T CP Head Coil

Indications for Use:

For use with a 1.5T Siemens Avanto/Espree or 3T Siemens Trio a TIM/Verio magnetic resonance scanner to produce diagnostic images of the head that can be interpreted by a trained physician.


Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K091114

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